DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

cc: HFI-35/FOI Staff
DWA

November 15, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-11

Peggy L. Coyne
President
Presidents Specialty Healthcare
715 Mt. View-Baken Park
Rapid City, South Dakota 57702

Dear Mrs. Coyne:

During our October 29, 1996, inspection of your medical gas manufacturing facility located in Rapid City, SD, our investigator documented deviations from the Current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations, Parts 210 and 211 (GMPR). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Deviations from GMPR include:

Failure to establish written procedures for transfilling operations.
Failure to document the daily calibration of the oxygen analyzer.
Failure to document testing of filled oxygen cylinders.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may

take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Minneapolis District Office, 240 Hennepin Avenue, Minneapolis, Minnesota 55401, Attention: Lawrence R. Murphy, Compliance Officer.

Sincerely yours,

John Feldman
Director
Minneapolis District

LRM/ccl